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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/472,110	12/27/1999	HERBERT E. SCHWARTZ	FZIO01000US4	8339

23910 7590 12/17/2003

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EXAMINER
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OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/17/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/472,110

Applicant(s)

SCHWARTZ ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 95-107 is/are pending in the application.
- 4a) Of the above claim(s) 95-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

### DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

#### Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1 and 18-20 and 107 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bonte et al., WO 97/01345.

Claim 1 is drawn to an ionically cross-linked gel comprising a polyacid - carboxymethylcellulose, carboxyethyl cellulose; a polyalkylene oxide- in the form of polypropylene oxide, polyethylene glycol, polyethylene oxide and a multivalent cation – in the form of a divalent cation.

Claims 18-20 are drawn to the composition of claim 1, wherein the multivalent cation is a divalent cation accompanied by an inorganic.

Bonte teaches a composition (example 7) containing a polyacid, specifically hyaluronic acid and a divalent cation with an accompanying inorganic ion in the form of magnesium silicate.

Bonte further teaches a polyalkylene oxide in the form of the copolymer methacryloyl ethyl betaine/ methacrylate.

**Claim Rejections - 35 U.S.C. § 103**

Claims 1-29 and 107 are rejected under 35 U.S.C. 103(a) as being obvious over Tapolsky et al., U.S. Patent No. 5,800,832 in combination with Jacob et al., U.S. 5,985,312.

Claim 1-17 and 28 are drawn to an ionically cross-linked gel comprising a polyacid - carboxymethylcellulose, carboxyethyl cellulose; a polyalkylene oxide- in the form of polypropylene oxide, polyethylene glycol, polyethylene oxide and a multivalent cation – in the form of a divalent cation.

Claims 18 – 23 are drawn to the composition of claim 1, wherein the multivalent cation is a divalent cation accompanied by an inorganic or organic anion.

Claims 24 and 25 are drawn to the composition of claim 1 wherein the pH is in the range of about 2.0 to about 7.5.

Claims 26 – 28 are drawn to the composition of claim 1 further comprising an antithrombogenic drug.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Tapolsky teaches a polymeric composition comprising carboxypolysaccharides such as carboxymethyl cellulose, hydroxyethylcellulose etc., and polyalkylene oxides such as polyethylene oxide (col. 6, lines 23-67), wherein the polyacid and polyalkylene compositions may comprise from 5% - 95% by weight and have molecular weights comprising 5kd to 700 kd for the polyalkylene and 5kd to 150 kd for the polyalkylene oxide (col.5, line 55 – col. 6, line 32). Tapolsky also teaches the addition of antithrombogenic agents such as salicylic acid and ibuprofen, col. 7, lines 18 and 60) however Tapolsky does not teach the addition of a multivalent/divalent cation.

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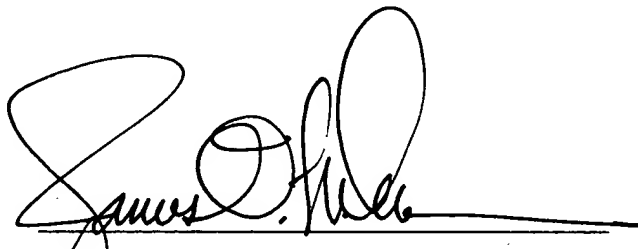
antithrombogenic agents such as salicylic acid and ibuprofen, col. 7, lines 18 and 60) however Tapolsky does not teach the addition of a multivalent/divalent cation.

Jacob teaches that the addition of multivalent metal compounds, i.e.  $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ ,  $\text{Fe}^{2+,3+}$ ,  $\text{Al}^{3+}$  to polymer compositions containing polyacids and polyalkylene oxides improves the bioadhesive properties of these compositions (col. 5, line 57 – col. 6, line 62) which adequately bridges the nexus between the prior art and the invention as claimed.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to incorporate a multivalent/divalent cation to a polyacid/polyalkylene composition.

A person of ordinary skill in the art would have been motivated to incorporate a multivalent/divalent cation to a polyacid/polyalkylene composition given the use of these multivalent cations to improve the bioadhesive properties of polyacid/polyalkylene compositions in the prior art.

Howard V. Owens  
Patent Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538. The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.